

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Investigation of the Comparative Effectiveness Between *Achillea wilhelmsii* Consumption and Counseling with Mindfulness-Based Cognitive Therapy (MBCT) Approach on Hot Flashes, Quality of Life and Sleep in Menopausal Women

#### Protocol summary

##### Study aim

Determining and comparing the effect of *Achillea wilhelmsii* and counseling with mindfulness-based cognitive therapy approach on hot flashes, quality of life and sleep in postmenopausal women

##### Design

The first group is 25 people treated with Yarrow Capsules. The second group is 25 people in the control group without treatment. They will receive only the routine care of the health center, and the third group is 25 people in the counseling group. Considering the effect size of 0.4, the sample size in each group was 22 people. According to the probability of falling, a total of 75 people will be included in the study.

##### Settings and conduct

After receiving permission to conduct the research and presenting it to Kerman University of Medical Sciences, the researcher refers to health centers under the auspices of Torbat Heydariyeh University of Medical Sciences and this clinical trial study will be a random sampling method. Menopausal women under the auspices of Torbat Heydariyeh health centers will be obtained through the Apple system.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Be literate and grow All women are 65-45 Have at least 20-20 hot flashes a day For one year after the last menstrual period Exclusion criteria: Absence from two sessions of medical counseling

##### Intervention groups

The first group is 25 people treated with Yarrow capsules the morning. The second group is the control group without treatment, they will receive only the routine care of the health center, and the third group is the counseling group.

##### Main outcome variables

Sleep quality: Quality of life: Flushing:

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210201050212N1**

Registration date: **2021-07-28, 1400/05/06**

Registration timing: **prospective**

Last update: **2021-07-28, 1400/05/06**

Update count: **0**

##### Registration date

2021-07-28, 1400/05/06

##### Registrant information

##### Name

omolbanin lotfi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5222 7100

##### Email address

o.lotfi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-06, 1400/05/15

##### Expected recruitment end date

2021-12-06, 1400/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigation of the Comparative Effectiveness Between Achillea wilhelmsii Consumption and Counseling with Mindfulness-Based Cognitive Therapy (MBCT) Approach on Hot Flashes, Quality of Life and Sleep in Menopausal Women

### Public title

The effect of yarrow on menopause

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Be literate All Women are 65-45 Have at least 3- 20 hot flashes a day For one year after the last menstrual period

#### Exclusion criteria:

Absence from two sessions of medical counseling Have a physical or mental illness Have a regular exercise program Taking psychotropic drugs Have a severely stressful event over the past month Has taken less than 80% of his medication Has used soy or phytoestrogens more than once in the past week Over the past week with a specific illness that is severely stressful or causing pain During the study, he had to use a special medication that caused sleep disturbances as well as hot flashes Have changed your sleeping place and place during the last week Used sleeping pills or hypnotics He has used psychedelic, sedative and anti-anxiety drugs Be addicted to drugs such as cigarettes and alcohol Use medications that cause sleep disturbances or insomnia History of yarrow or any of its components, people with allergic asthma, seizures, liver disease or cancer Take any estrogen-based medication to treat menopausal complications (osteoporosis, hot flashes) or other interfering medications such as tibolone with a night shift job. Menopause due to bilateral removal of the ovaries or undergoing chemotherapy Treatment for mental disorders or hot flashes in the last 60 days Hormone Therapy Use of hormonal contraceptives Taking selective estrogen receptor modulators or aromatase inhibitors over the past two months Have severe depression Have a severe current illness Suicide attempt in the last 3 weeks Having bipolar disorder or other mental disorders throughout life Uncontrolled blood pressure Taking tamoxifen, raloxifene, antidepressant, clonidine in the last two months

### Age

From **45 years** old to **65 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **75**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Random permutation will be performed using the block

method: For random assignment, triple blocks with three patients and a table of single-digit random numbers are used, so that for a random number, a triple block, and for a random number, two triple blocks, and so on, the numbers zero, seven, and eight are used. No, we will. ABC for digit 1 ACB for figure 2 BAC for digit 3 BCA for figure 4 CAB for digit 5 CBA for figure 6 And we ignore the numbers 0, 7, 8 and 9. The reason for using the random permutation block method is that the number of people in the groups is equal.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

##### Street address

No.9,Kashini Ave

##### City

Totbat e heydarieh

##### Province

Razavi Khorasan

##### Postal code

9516817311

#### Approval date

2021-06-14, 1400/03/24

#### Ethics committee reference number

IR.KMU.REC.1400.174

## Health conditions studied

### 1

#### Description of health condition studied

Investigation of the comparative effectiveness between Achillea wilhelmsii consumption and counseling with mindfulness-based cognitive therapy (MBCT) approach on hot flashes, in menopausal women

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Comparative study of the effect of Achillea wilhelmsii and counseling with mindfulness-based cognitive therapy approach on quality of life in postmenopausal women

## ICD-10 code

### ICD-10 code description

## 3

### Description of health condition studied

Comparative study of the effect of Achillea wilhelmsii and counseling with mindfulness-based cognitive therapy approach on sleep quality in postmenopausal women

## ICD-10 code

### ICD-10 code description

## Primary outcomes

## 1

### Description

Flush score

### Timepoint

Measure hot flashes before the study and at the end of the first and second months

### Method of measurement

Flushing severity questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Achillea wilhelmsii capsule (2 mg daily in the morning and evening for 2 months) which contains Achillea wilhelmsii which has phytoestrogenic properties and is produced by Kerman School of Pharmacy

### Category

Lifestyle

## 2

### Description

Intervention group: Counseling group: Eight sessions of 120 to 150 minutes. With 45 minutes a day of exercise, which can be accompanied by a one-day program of mindfulness guided in week 6. In the first 4 sessions, the focus is on inner experiences and in the second half on the challenges of life. Mindfulness training will be short.

### Category

Behavior

## 3

### Description

Control group: Does not receive any intervention

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Torbat Heydariyeh Health Center

#### Full name of responsible person

Lotfi Omolbanin

#### Street address

No.9,Kashani Ave

#### City

Torbat Heydariyeh

#### Province

Razavi Khorasan

#### Postal code

9516817311

#### Phone

+98 51 5222 7100

#### Email

olotfi1398@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Dr. Abbas Pardakhti

#### Street address

No.9,Kashani Ave

#### City

Torbat Heydarieh

#### Province

Razavi Khorasan

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#### Phone

+98 51 5222 7100

#### Email

olotfi1398@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Kerman University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Omolbanin Lotfi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

No.1,GHarani Ave,Torbat Heydariyeh University of  
Medical Sciences

**City**

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**Province**

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**Postal code**

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**Fax****Email**

o.lotfi1398@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Omolbanin Lotfi

**Position**

Student

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Master

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available